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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-20

May 22, 2000

Bruce E. Burnett, President/Owner
Miter, Inc.
4126 N. Blue Heron Drive
Warsaw, Indiana 46580

Dear Mr. Burnett:

We are writing you because on February 28 – March 3, 2000, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving your products known as the "Augmen" and "Peri-Oss" endosseous dental implants. These products are made for and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body.

The inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System (QS) regulation found in Title 21, Part 820 of the U.S. Code of Federal Regulations. This warning letter also acknowledges your letter of March 17, 2000, written in response to the FDA-483, as well as any responses you made during the closing discussion when the FDA-483 was issued.

The following deviations were identified:

1. Failure of management with executive responsibility to ensure that the quality policy has been established, implemented, understood, and followed, to demonstrate your commitment to quality, at all levels of the organization, as required by 21 CFR 820.20(a).
   For example:

   a. There is no designated management representative responsible for ensuring that the quality system requirements are effectively established and maintained.
      21 CFR 820.20(b)(3)(i)

b. There is no management review of the suitability and effectiveness of the quality system to ensure that the quality system satisfies the requirements. 21 CFR 820.20(c)
c. There is no quality plan that defines the quality practices, resources, and activities relevant to the devices that are designed/manufactured. 21 CFR 820.20(d)
d. There are no quality procedures and instructions established 21 CFR 820.20(e)

Your response indicates that you have now established all procedures, plans, and policies as required, and designated yourself as management representative. This would appear to address these deficiencies. We will evaluate these corrections during our next inspection.

2. Failure to have adequate procedures to identify training needs to ensure that personnel are trained to adequately perform their assigned responsibilities. For example, there is no documentation to show that the designated management representative has been trained in proper application of the quality system regulation. 21 CFR 820.25(b)

   Your response indicates that you are committed to self-study and plan formal seminar attendance for proper application of the quality system regulation. You did not include information on where, or when a seminar is scheduled, and whether you have made arrangements to attend.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by regulation. For example, your products are manufactured by a contract manufacturer and sterilized by a contract sterilizer. In addition, all raw material and finished product testing is performed by outside contractors. 21 CFR 820.50(a)

   a. There is no documented evidence that you have evaluated the ability of these contractors to meet the specified requirements.
   b. There is no assurance that distributed product is adequately sterilized since no documents exist to show that the sterilization cycle has been validated.
   c. There are no documents to show that bioburden tests have been conducted, and that post sterilization packaging tests have been performed.
   d. There is no written agreement with the contract sterilizer to define the type and extent of control to be exercised over the product.

   Your response indicates that you have contacted the sterilizer and will implement a formal agreement within 30 days. You also indicate that a customer specification requirement has been in effect with the sterilizer since 1998. Your response states that post-packaging integrity testing is performed/documented at the contract packager. You also indicate that bioburden testing will be done periodically to assure safe levels during handling. However, your response lacks an indication of specific timetables for bioburden testing, accompanying documentation for sterilization cycle documentation, and post packaging integrity testing documentation.

4. There is no documentation that finished device packaging and shipping containers have been designed and constructed to protect the devices from alteration or damage during processing, storage, handling, and distribution as required by 21 CFR 820.130.

   Your response refers to packaging specifications in the PMA, including an improvement to the boxes approximately eight years ago (1992) by [redacted]. You also indicate that the contractors control the documentation of this packaging.

   Mr. Calafactor's report states that at various times he asked about specifications for Peri-Oss and Augmen. You referred to the PMA, however you were unable to identify the appropriate pages to him. You provided copies of selected pages from the PMA, including a five page Table of Contents. This table lists packaging information under Item 11.F. in Volume 4 - Tab Item 11, Pages 83-90. You must examine this material for any specifications that were established and tested for suitability. These specifications then must be incorporated into the Device Master Record and History Record to ensure they are carried through in the manufacturing process. You should determine if the current packaging adheres to those specifications. Your Master Record must include any appropriate specifications for packaging, and the History Record must document adherence to them.

5. There are no established written procedures addressing:
   a. Design control operations including design changes to existing medical devices. 21 CFR 820.30(i).
   b. Purchasing controls including evaluations of component and raw material suppliers, and contract manufacturers, sterilizers and test laboratories. 21 CFR 820.50(a).
   c. Production and process changes. 21 CFR 820.70(b).
   d. Handling, storage, distribution, and environmental control conditions. 21 CFR 820.140, 150, & 160.
   e. Corrective and preventive actions. 21 CFR 820.100.
   f. Handling of complaints, medical device reporting events (MDR's) and corrections and removals. 21 CFR 820.198.
   g. Procedures for conducting internal quality audits. 21 CFR 820.22.

   Your response to these observations was that the appropriate procedures have been written and included in the Quality Assurance Program Manual. We will evaluate these revised procedures during our next inspection.

6. The Device Master Record fails to address final release specifications for the Peri-Oss and Augmen bone grafting materials. 21 CFR 820.181(a)

7. The Device History Records fail to document the final acceptance/rejection of the Peri-Oss and Augmen bone grafting materials. 21 CFR 820.184.

   Your response to points 7e and 8 of the FDA-483 indicate you have established a dedicated release specification form. This would appear to address the above two deficiencies. Please forward copies of the revised master and history records for Augmen and Peri-Oss.

In addition to the adulteration charges just listed, the inspection also revealed that these devices are misbranded within the meaning of section 502(o) of the Act in that your firm has not registered, on an annual basis, with the FDA as set forth in section 510 of the Act. The Cincinnati District Office of the FDA classified the Miter Co., Columbus, OH; under number 1523292, as Out Of Business in 1990. On January 20, 1993 Investigator William R. Brubaker of the FDA Detroit District inspected your firm in Warsaw, IN. He reported this under a new Central File Number, 1834009 and he reported that your firm was not registered. On October 10, 1995 Mr. Brubaker again inspected your firm and reported it was not registered. He referred this to the Detroit Registration Monitor whose records indicate that a registration form was sent to you on November 20, 1995. Nothing in our records indicates that you were notified of the new Central File Number, 1834009, which is also used as the registration number. Nevertheless, you are responsible for assuring that your firm is registered. Currently, an outside contracting company handles distribution of device firm registration forms. They can be reached at (301) 495-7726 or FAX (301) 495-4660. You must obtain and complete the form, and return a copy to this office as well as sending the original to the Rockville, MD address on the form.

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

In summary, listed below are the items that I have requested be sent to me to assure the corrective actions are being implemented:

a. Details of your plans to attend a formal seminar covering quality system management.
b. Copies of Augmen and Peri-Oss device master and history records showing the incorporation of specifications from the PMA.
c. Copy of a completed device firm registration form.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of any additional steps you have taken to correct the noted deviations and to prevent their recurrence.

Your response should be directed to this office to the attention of Mr. Melvin O. Robinson, Compliance Officer. (313) 226-6260 Extension 128.

Sincerely yours,

John P. Dempster

for Raymond V. Mlecko
District Director
Detroit District